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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,229	06/26/2003	Manfred Bohn	3804.1596-01	4228

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EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1618

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,229

Applicant(s)

BOHN ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/077194.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

RCE acknowledged

A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/5/2006 has been entered.

Declaration

1. Acknowledgement is made of Declaration filed 1/5/06.

Status of Application

1. The claims 14-29 are pending and presented for the examination.

Claim Rejections - 35 USC 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 14-29 are rejected under 35 U.S.C. 103(a) as being obvious over Dittmar et al(US4,185,106) in view of Squiquera et al(1996,July) and Shoshan (WO96/290455) and Thorel(FR2685867).

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The claims are drawn to a method of treating seborrheic dermatitis using the composition consisting essentially of at least one 1-hydroxy-2-pyridone of general formula I as recited in the claim 14.

US'145 teaches an effective anti-dandruff treatment using a pharmaceutical composition containing 1-hydroxy-2-pyridones (e.g. ciclopirox(1-hydroxy-4-methyl-6-cyclohexyl-2-pyridone) or octopirox(1-hydroxy-4-methyl-6-(2,4,4-trimethyl-pentyl)-2-pyridone)) as active agent, see abstract and col 2.

Applicant's claims differ because they are directed to a method of treating seborrheic dermatitis.

However, it would have been obvious to one of ordinary skill in the art at that time of the invention was made to extend the teaching to include seborrheic dermatitis when Dittmar(US'106) is taken in view of Squiquera et al(1996,July) and Shoshan(WO'455) because latter references remedy the deficiency of Dittma's teaching.

Firstly, Squiquera et al(1996,July) teaches that dandruff has been associated with a local increment in the number of pityrosporum yeasts. Furthermore, antidandruff treatment can be effectively achieved by ciclopirox olamine(OCT) due to its antifungal and antimycotic activities, see abstract and page 29, 3rd paragraph. Although Squiquera et al(1996,July) does not directly mention that seborrheic dermatitis has been treated with OCT, it does teach seborrheic dermatitis and dandruff is caused by pityrosporum yeasts.

Second, Shoshan(WO'455) also teaches that dandruff is seborrheic dermatitis of the scalp, and is precursor of alopecia(baldness) and associated with yeast Pityrosporum, see page 1, lines 7-17.

Thorel(FR'867) teaches a combination of 1-hydroxy-2-pyridone and undecylenic acid is effectively used in the treatment of dandruff or seborrheic dermatitis secondarily infected by Pityrosporum.

When these teachings are combined, it is readily apparent that dandruff which is a sign and symptoms of seborrheic dermatitis caused by Pityrosporum yeast. Thus, one would have been motivated to employ 1-hydroxy-2-pyridone to treat seborrheic dermatitis because the efficacy is proven by treating symptoms and also inhibition of causative organism, Pityrosporum yeast. One would have been motivated to choose 1-hydroxy-2-pyridone as a drug of choice because its proven safety and therapeutic efficacy as taught by references mentioned above. Due to the toxicities and difficulties for manufacturing pharmaceutical product which are the main drawback factors associated with other antimycotic, antifungal and antibacterials, one would have been motivated to select 1-hydroxy-2-pyridone for treating seborrheic dermatitis, with reasonable expectation of success.

All other critical elements required by the instant claims are well taught in the cited references and thus, the claimed subject matter is not patentably distinct over the prior art of the record.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same

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ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

3. No claim is allowed. Having carefully reviewed applicants' Request for reconsideration, Applicant's arguments are moot in view of the new ground(s) of rejection.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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VICKIE KIM
Vickie Kim
PRIMARY EXAMINER
Primary Patent Examiner
April 3, 2006
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